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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/983,025	10/22/2001	Claus Oxvig	OXVIG=1A	7756

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BROWDY AND NEIMARK, P.L.L.C.  
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EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/983,025	<b>Applicant(s)</b> OXVIG ET AL.	
	<b>Examiner</b> Delia M. Ramirez	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12, 18, 19, 30-47, 49-52, 55-58, 62, 75, 83, 87, 90-93, 95-101, 105, 108, 110 and 111 is/are pending in the application.
- 4a) Of the above claim(s) 30-47 and 62 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 90-93, 95-101, 110 and 111 is/are allowed.
- 6) ☒ Claim(s) 105 is/are rejected.
- 7) ☒ Claim(s) 12, 18, 19, 49-52 and 55-58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of the Application***

Claims 12, 18-19, 30-47, 49-52, 55-58, 62, 75, 83, 87, 90-93, 95-101, 105, 108, and 110-111 are pending.

Applicant's amendment of claims, cancellation of claims 102-104, 106-107, and addition of claims 110-111 in a communication filed on 8/8/2005 is acknowledged.

In view of Applicant's response and amendments filed, the Examiner contacted Mr. Iver Cooper on 10/8/2005 to request permission to amend claims 12, 83, 105, and cancel withdrawn claims to place the application in condition for allowance. Mr. Cooper requested rejoinder of all method claims pending.

Claims 12, 18-19, 75, 83, 87, 90-93, 95-101, 105, 108, and 110-111 are now directed to a product free of the prior art of record and would be allowable if amended as previously indicated to overcome the objections and new matter rejection previously applied. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 49-52 and 55-58, directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 49-52 and 55-58 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 30-47 and 62 are not directed to the process of making or using the patentable product, will not be rejoined. It is noted that claims 30-41 are directed to a method for detecting the product, claims 42-47 are directed to a method of diagnosing a clinical condition in an individual by detecting the product, and claim 62 is directed to a method of purifying the product. These methods are neither methods of use or manufacture of the product. Instead, a method for detecting the product, or a method of diagnosing a condition by detecting the product are methods of use of an antibody, an agent which binds the product, or a polynucleotide (i.e., probe which detects mRNA), whereas a method for purifying the product is a method of use of an antibody or an agent which binds the product.

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The requirement for restriction between the product claims and the rejoined process claims 49-52 and 55-58 is hereby withdrawn. This application contains claims 30-47 and 62 drawn to an invention non-elected with traverse in a communication filed on 11/24/2003. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 12, 18-19, 49-52, 55-58, 75, 83, 87, 90-93, 95-101, 105, 108, and 110-111 are under consideration and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### *Specification*

1. The use of trademarks has been noted in this application. See, for example, "Invitrogen" in page 59, line 23, "Qiagen" in page 61, line 5, "Stratagene" in page 60, line 8, etc. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Applicant's cooperation is requested in reviewing the specification for other trademarks that may be present in the specification and making the appropriate correction(s).
2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, page 56, line 24, page 51, line 2, page 54, line 17. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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***Claim Objections***

3. Claim 12 remains objected to due to the recitation in line 3 of “a polypeptide of (a)”. As previously indicated in the Non Final Action mailed on 5/18/2005, it is suggested the term be amended to recite “the polypeptide of (a)” since the polypeptide has been previously defined in (a). Appropriate correction is required.

4. Claim 83 remains objected to due to the recitation of “sequence which differs from said sequence (a)”. As previously indicated in the Non Final Action mailed on 5/18/2005, for clarity and consistency, it is suggested the term be amended to recite “sequence which differs from that of the polypeptide of (a)”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112, First Paragraph***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 105 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as it contains new matter.

7. Applicants have indicated that the recitation in the specification of “2-5” is a typo and that “1-5” is the intended range. Applicants submit that if necessary, they would agree to an Examiner’s amendment to the claim.

8. Since the pending claims are not ready for allowance, no Examiner’s amendment can be made regarding claim 105. Thus, applicants are required to cancel the new matter in response to this Office Action.

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***Claim Rejections - 35 USC § 102***

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
10. Claims 12, 18-19, 75, and 105 were rejected under 35 U.S.C. 102(a) as being anticipated by Farr et al. (Biochim. Biophys. Acta, 1493:356-362, October 2, 2000; cited in the IDS; SPTREMBL accession number Q9H4C9). This rejection has been discussed at length in previous Office Actions mailed on 2/10/2004, 9/7/2004, 2/9/2005, and 5/18/2005.
11. Claim 12 (claims 18-19, 75 and 105 dependent thereon) has been amended such that it encompasses a polypeptide having proteolytic activity against IGFBP-5 and having at least 95% sequence identity to residues 234-1791 of SEQ ID NO: 2 but differing from a polypeptide consisting of amino acids 234-1791 of SEQ ID NO: 2 solely by one or more conservative substitutions. Since the polypeptide of Farr et al. and the claimed polypeptide differ by conservative and non-conservative amino acid substitutions, and Farr et al. does not suggest a polypeptide as claimed, the instant rejection is hereby withdrawn.

***Allowable Subject Matter***

12. Claims 12, 18-19, 49-52, 55-58, 75, 83, 87, 90-93, 95-101, 105, 108, and 110-111 appear to be allowable over the prior art of record.

***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing

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date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
October 13, 2005

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1800-  
1652